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CENTRAL RESEARCH AND DEVELOPMENT DEPARTMENT

March 15, 1982

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MEMO TO: J. W. RAINES
PPD, M-5625

FROM : B. C. MCKUSICK

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REPORT OF FC-143 TERATOGENIC STUDIES TO EPA

On March 12 Frank D. Griffith and William H. Pearlson of 3M and I reported results of teratogenic studies on three fluoro-surfactants to EPA. This was a follow-up to 8e notifications to EPA by 3M reporting teratogenic findings on a fluoroalcohol, a fluorosulfonate, and ammonium perfluorooctanoate (FC-143; C-8).

Thirteen people from the EPA Office of Toxic Substances, including Frank Kover, Terry O'Bryan, Joseph Seifter (an in-house toxicology consultant), and Elaine Francis (a teratologist) met with us for nearly two hours. Pearlson said that although full teratogenic studies on the alcohol and sulfonate and a dose-ranging study on FC-143 had earlier indicated that all three caused an eye defect in rat fetuses, 3M now believed that none of the substances caused this defect. He gave EPA copies of reports on two 3M studies of FC-143 that were subsequent to the 8e notifications, and said that no significant teratogenic effects were noted, in the eye or elsewhere. I supported his position by giving EPA reports of the two negative teratogenic studies of FC-143 by Haskell Lab. I said that few substances had been so extensively examined for teratogenic effects as FC-143, with a total of four full-scale studies carried out in two laboratories in two species of mammal by two routes of administration; that although the eye had received more attention than usual because of the initial indications of eye defects, both skeletal and soft tissue had been thoroughly examined for teratogenic effects and then none had been found; that the absence of eye defects had been reinforced by examining the eyes of juvenile rats born of exposed mothers and finding their eyes normal.

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Pearlson explained how, after FC-143 was shown not to be a teratogen, 3M reexamined the data on the other two fluorosurfactants, and concluded that they did not cause eye defects after all (he pointed out that the alcohol caused defects in other organs at high exposure levels). A few of the EPA people seemed to find it hard to understand how highly positive findings with good dose-response relationship could subsequently turn out to be negative. I don't think Pearlson and Griffith completely convinced the skeptics by their response, which included the factor of bias through not examining the slides blind. Hence, although the EPA people seemed to agree with the conclusion that there is no good evidence that FC-143 is a teratogen, some were hesitant about agreeing that the other two fluorosurfactants had not caused eye defects in rat fetuses.

EPA officials said that there is no mechanism for withdrawing an 8e notification or for EPA to declare it not a cause for concern. However, the 3M and Du Pont reports of studies on FC-143 will be placed in the same file as the 8e notice, and should anyone ask about the 8e notice on FC-143, he will be told about the conclusions of the reports.

BCM/bjd

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